

Attachment 2

EFFECT OF PRODUCT FORMULATION ON TRICLOSAN EFFECTIVENESS

Michael L. Barnett, D.D.S.

An assessment prepared for the Colgate-Palmolive Company

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Although the antimicrobial triclosan is incorporated in a variety of product types, the development of triclosan-containing oral care products with significant antiplaque and gingivitis effectiveness has been especially challenging. Dentifrice formulations, in particular, are extremely complex and must be exquisitely optimized in order to assure, for example, that the triclosan is not bound to other components, such as surfactants, and that the triclosan will be substantive in the mouth following product use and thereby continue to exert an effect¹⁻⁴. This being the case, there have been only a few effective antiplaque/gingivitis triclosan-containing products marketed worldwide, and these tend to be based on proprietary, patented formulations.

Oral care products companies have taken two approaches to developing effective triclosan-containing dentifrices. The first, used by Colgate-Palmolive Co. for its Total[®] products, is to incorporate ingredients (i.e., a copolymer such as Gantrez[®]) that will enhance the delivery and retention of triclosan to oral surfaces. This formulation has been granted a US patent⁵ and is supported by numerous long-term plaque/gingivitis clinical trials^{6,7}. In addition, this formulation was approved by the FDA for marketing in the U.S. via the New Drug Application (NDA) process⁸ and was granted the American Dental Association's Seal of Acceptance.

The second approach, used by Unilever, is to incorporate a second antimicrobial agent, zinc citrate, to increase overall product effectiveness. The Unilever products, too, are based on patented formulations⁹ and supported by clinical trial data¹⁰⁻¹⁶. However, these are combination products containing two antimicrobial agents, triclosan and zinc citrate, and are not marketed in the U.S.

A third approach was taken by Procter and Gamble in the development of triclosan/pyrophosphate dentifrice formulations. However, these products lack sufficient gingivitis effectiveness^{17,18} and are not marketed in the U.S.

The experience with formulating triclosan into effective antiplaque/gingivitis products suggests that while the individual Colgate and Unilever dentifrices might be generally accepted as effective, difficulties in achieving optimized formulations and the very different approaches taken by the two companies to achieve product effectiveness preclude classifying the ingredient triclosan by itself as generally effective at this time. The activity of this agent is clearly dependent upon the way in which it is formulated and the Colgate triclosan dentifrice, whose NDA is based on the overall formulation rather than the active ingredient *per se*, is the only effective triclosan-containing gingivitis dentifrice marketed today in the U.S. Unlike an OTC monograph ingredient review, the NDA does not require a final formulation test ("performance test") for comparing new formulations to the clinically tested standard, nor should it. It is unlikely that any clinical test short of the 6-month clinical trials required for evaluation of antiplaque and gingivitis effectiveness would be able to accurately evaluate any new triclosan-containing products. However, the requirement of such extensive studies prior to marketing, while the standard for an NDA and the initial OTC ingredient review, is clearly inconsistent with the intent of an OTC monograph. Until such time as evidence is presented to demonstrate that triclosan can be *readily* formulated in

effective antiplaque/antigingivitis products as a single active ingredient **and** a clinically relevant, validated final formulation test procedure specific for triclosan is established, it is my opinion that it would not be appropriate to consider triclosan for inclusion in the OTC monograph being developed for such products¹⁹ as there would otherwise be no reasonable assurance that any newly and differently formulated products would be clinically effective.

References

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9. US Patent Number 4,656,031, Dentifrice Composition; April 7, 1987; US Patent Number 4,749,561, Dentifrice compositions. June 7, 1988.
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12. Saxton CA, van der Ouderaa FJ. The effect of a dentifrice containing zinc citrate and Triclosan on developing gingivitis. *J Periodont Res* 1989; 24: 75-80.
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19. Federal Register 68: 32243, May 29, 2003.

CURRICULUM VITAE

MICHAEL L. BARNETT, D.D.S.

ADDRESS:

9 Bennington Road
Morristown, NJ 07960-6125
Telephone: (973) 829-6966
e-mail: mlbgums@aol.com

EDUCATION:

1960-63 Columbia College, New York City
1963-67 School of Dental and Oral Surgery, Columbia University, NYC - D.D.S.
1967-68 Postdoctoral Fellowship, Department of Oral Biology, School of Dentistry, University of Washington, Seattle, WA
1970-73 Postdoctoral Fellowship, Harvard School of Dental Medicine, Boston, MA - Certificate in Periodontology and Oral Medicine

MILITARY SERVICE:

1968-70 Captain, U.S. Army Dental Corps, Chief of Oral Medicine, Fort Lewis, WA

APPOINTMENTS:

1964-65 NIH Summer Research Fellow, Department of Physiology, College of Physicians & Surgeons, Columbia University, NY
1967-68 Postdoctoral Fellow, Department of Oral Biology, University of Washington School of Dentistry, Seattle, WA
1968-70 General Dentistry Residency Faculty Member (Oral Medicine), Fort Lewis Dental Activities, Tacoma, WA
1970-73 Research Fellow in Periodontology and Oral Medicine, Harvard School of Dental Medicine, Boston, MA
1973-74 Assistant Professor, Department of Periodontics, New Jersey Dental School, UMDNJ, Jersey City, NJ
1974-77 Visiting Lecturer in Periodontology, Harvard School of Dental Medicine, Boston, MA
1974-75 Assistant Professor, Department of Periodontics, School of Dentistry, State University of New York, Buffalo, NY
1975-79 Associate Professor, Department of Periodontics, School of Dentistry, State University of New York, Buffalo, NY
1975-79 Associate Consulting Dentist, Department of Dentistry, E. J. Meyer Memorial Hospital, Buffalo, NY
1979-82 Associate Professor and Coordinator of Postgraduate Education, Department of Periodontics, School of Dentistry, University of Louisville, Louisville, KY
1982-87 Chairman, Department of Dentistry and Director, General Practice Residency, Morristown Memorial Hospital, Morristown, NJ
1982-87 Associate Clinical Professor of Dentistry, Division of Periodontics, School of Dental and Oral Surgery, Columbia University, New York, NY
1983-87 Director, Dental Program for the Developmentally Disabled, Department of Dentistry, Morristown Memorial Hospital, Morristown, NJ

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1987-99	Consulting Staff, Department of Dentistry, Morristown Memorial Hospital, Morristown, NJ
1987-90	Associate Director, Dental Affairs, Warner-Lambert Company, Morris Plains, NJ
1991-98	Senior Director, Dental Affairs, Warner-Lambert Company, Morris Plains, NJ
1992-04	Visiting Professor, Department of Periodontics, New Jersey Dental School- UMDNJ, Newark, NJ
1998 -00	Senior Director, Dental Affairs/Oral Technology Development, Warner-Lambert Company, Morris Plains, NJ
2000-01	Senior Director, Dental Affairs/Oral Technology Development, Pfizer Consumer Healthcare, Morris Plains, NJ
2002-	Independent Consultant to the Oral Care Products Industry, Morristown, NJ
2004-	Clinical Professor of Oral Biology and Interim Associate Dean for Research, New Jersey Dental School-UMDNJ, Newark, NJ

MEMBERSHIPS:

American Dental Association
American Academy of Periodontology
American Association for Dental Research
American Association for the Advancement of Science
New Jersey Dental Association, Tri-County Dental Association

HONORS:

1960-67	New York State Regents Scholarship
1967	Block Drug Award
1970	U.S. Army Commendation Medal
1986	Fellow, American College of Dentists
1998	Fellow, American Association for the Advancement of Science
2002	Jack Hein Public Service Award, American Association for Dental Research

LICENSES: New Jersey

BOARDS:

Northeast Regional Board
National Board of Dentistry

SERVICE TO PROFESSIONAL ORGANIZATIONS:

American Association for the Advancement of Science
1992-95 Member, Section on Dentistry Electorate Nominating Committee (Chair 1994-95)
1996-99 Council Representative, Section on Dentistry
American Association for Dental Research
1980-81 President, Louisville Section
1981-82 Periodontal Research Group Program Committee
1989-92 Member, Exhibits Committee
1989-90 Secretary-Treasurer, NJ Section

1990-91 Vice-President, NJ Section
1991-92 President, NJ Section
1992-96 Councilor, NJ Section
1992-00 Member, National Affairs Committee
1992- Member, AADR Cohorts
1996-00 Councilor, Institutional Member Section
1996-00 Ad hoc Industry Affairs Advisory Committee (Chair, 1996-98)
1997-99 Member-at-Large, Board of Directors
2000-04 Councilor, New Jersey Section
American College of Dentists
1989-91 Member, Executive Board, NJ Section
1989-91 Secretary-Treasurer, NJ Section
American Dental Association
1991-01 Member (non-voting), Selection Committee, Dr. Norton M. Ross
Award for Excellence in Clinical Research
1999-04 Member, Board of Directors, ADA Health Foundation
1999-01 Member, US Delegation to ISO/TC106 Meetings
Columbia University School of Dental and Oral Surgery
1992-94 Executive Member, Irwin D. Mandel Research Endowment Fund
1996- Dean's Advisory Council and Campaign Committee
Forsyth Dental Center
1990-91 Executive Member, John W. Hein Research Fellowship Committee
1992-98 Member, Board of Overseers
Friends of the National Institute of Dental Research
1998-2001 Member-at-Large, Executive Committee, Board of Directors
(Secretary 1999-00)
Harvard School of Dental Medicine
1980-83 Associate Chairman, The Alumni-Faculty Campaign
National Institute of Dental Research
1994 Ad hoc Reviewer, Small Business Innovation Research Grants
New Jersey Commission on Science and Technology
1999 Ad hoc Reviewer, R&D Excellence Program
University of Medicine and Dentistry of New Jersey
2002- Member, Dean's Advisory Board, New Jersey Dental School
2004- Member, Strategic Planning Subcommittee on Strategic
Connections to New Jersey's Pharmaceutical Industry

EDITORIAL ACTIVITIES:

1965-67 Assistant Editor, Journal of Oral Pharmacology and
Pharmacotherapeutics
1966-67 Manuscript Editor, Pharmacology for the Dental Hygienist, Kutscher,
A.M., et al, eds. Philadelphia; Lea & Febiger, 1967
1977-81 Ad hoc Reviewer, Archives of Oral Biology, Journal of Dental Research
1991-95 Ad hoc reviewer: Journal of Periodontology; Archives of Oral Biology
2002- Manuscript reviewer, Journal of the American Dental Association

PRIVATE PRACTICE EXPERIENCE:

I have been a participant in the intramural faculty practice plan at each of the schools
or hospitals at which I have been between 1973 and 1987.

COMMITTEE ASSIGNMENTS:

Harvard School of Dental Medicine
Dean's Faculty Committee
Undergraduate Admissions Committee

New Jersey Dental School (1973-74)
Executive Faculty Committee
Curriculum Committee
Chairman, Subcommittee on Curricular Evaluation
Search Committee for Chairman of Periodontics

School of Dentistry, State University of New York at Buffalo
Curriculum Committee
Facilities Planning Committee
Student Research and Honors Committee
Research Library Committee

School of Dentistry, University of Louisville
Postgraduate Academic Advisory Committee (Chairman, 1980-81)
Search Committee for Chairman of Physiology
Board of Governors, Faculty Practice Plan

Morristown Memorial Hospital
Medical-Dental Staff Executive Committee
Medical Education Committee
Long Range Planning Committee
Medical Isotope and Radiation Safety Committee
Developmental Disabilities Advisory Committee
Diabetes Education Advisory Committee
Outpatient Services Committee
Grants Committee
Research Advisory Committee
Institutional Review Board
Cancer Committee

GRANTS AND CONTRACTS:

1974-79	"Role of Mast Cells in Gingival and Periodontal Lesions", National Institute of Dental Research, DE-04162, \$22,500
1979-80	"Characterization of Surface Antigens of <u>S. Mutans</u> ", National Institute of Dental Research, DE-05017, \$29,568 (Co-Investigator)
1974-76	"Studies on the Ultrastructure of Human Gingival Epithelium", BRSG/NSF and Special Funds, SUNY at Buffalo, \$3,000
1980-81	"Ultrastructural and Clinical Studies of Periodontal Diseases", BRSG Funds, University of Louisville School of Dentistry, \$5,000
1983-87	"Dental Program for the Developmentally Disabled", Division of Mental Retardation, New Jersey Department of Human Services, Contract No. EP094PC, \$100,264 per year
1984-87	"Residency Training in the General Practice of Dentistry", Division of Associated and Dental Health Professions, Department of Health and Human Services, D30 DHI2079, \$150,409

PUBLICATIONS:

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4. Barnett, M.L. and Szabo, G.: Effect of vitamin A on epithelial morphogenesis in vitro. Fine structural changes in explants of adult mammalian skin. *Exptl. Cell Res.* 76:118-126, 1973.
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37. Fine, D.H., Furgang, D., Barnett, M.L., Mendieta, C., Meyers, R., Olshan, A., and Vincent, J.: Efficacy of preprocedural rinsing with an antiseptic in reducing viable bacteria in dental aerosols. *J. Periodontol.* 63:821-824, 1992.
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39. Fine, D., Mendieta, C., Barnett, M., Furgang, D., and Vincent, J.: Endotoxin levels in periodontally healthy and diseased sites: correlation with levels of Gram-negative bacteria. *J. Periodontol.* 63:897-901, 1992.

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46. Fine, D.H., Korik, I., Furgang, D., Myers, R., Olshan, A.M., Barnett, M.L.: Assessing pre-procedural subgingival irrigation and rinsing with an antiseptic mouthrinse to reduce bacteremia. J. Amer. Dent. Assoc. 127:641-646, 1996.
47. Barnett, M.L.: Suitability of gingival indices for use in therapeutic trials: Is bleeding a *sine qua non*? J. Clin. Periodontol. 23:582-586, 1996.
48. Riep, B., Bernimoulin, J-P., and Barnett, M.L.: Comparative antiplaque effectiveness of an essential oil and an amine fluoride/stannous fluoride mouthrinse. J. Clin. Periodontol. 26:164-168, 1999.
49. Pan, P., Finnegan, M.B., Sturdivant, L., and Barnett, M.L.: Comparative antimicrobial activity of an essential oil and an amine fluoride/stannous fluoride mouthrinse *in vitro*. J. Clin. Periodontol. 26:474-476, 1999.
50. Fine, D.H., Furgang, D., Barnett, M.L., Drew, C., Steinberg, L., Charles, C.H. and Vincent, J.W.: Effect of an essential oil-containing antiseptic mouthrinse on plaque and salivary *Streptococcus mutans* levels. J. Clin. Periodontol. 27:157-161, 2000.
51. Pan, P., Barnett, M.L., Coelho, J., Brogdon, C. and Finnegan, M.B.: Determination of the *in situ* bactericidal activity of an essential oil mouthrinse using a vital stain method. J. Clin. Periodontol. 27:256-261, 2000.
52. Whitaker, E.G., Pham, K., Feik, D., Rams, T.E., Barnett, M.L. and Pan, P.: Effect of an essential oil-containing antiseptic mouthrinse on induction of platelet aggregation by oral bacteria *in vitro*. J. Clin. Periodontol. 27:370-373, 2000.
53. Fine, D.H., Furgang, D. and Barnett, M.L. Comparative antimicrobial activities of antiseptic mouthrinses against isogenic planktonic and biofilm forms of *Actinobacillus actinomycescomitans*. J. Clin. Periodontol. 28:697-700, 2001.
54. Barnett, M.L. University-industry relationships in dentistry: past, present, future. J. Dent. Educ. 66:1163-1168, 2002.
55. Barnett, M.L. Coordination meeting on oral health and systemic health. Periodontal Medicine: Health Policy Implications (meeting summary). J. Periodontol. 74:1081-1086, 2003.
56. Barnett, M.L. The role of therapeutic antimicrobial mouthrinses in clinical practice: control of supragingival plaque and gingivitis. J.A.D.A. 134: 699-704, 2003.
57. Barnett, M.L. and Pihlstrom, B. Methods for enhancing the efficiency of dental/oral health clinical trials: Current status, future possibilities (workshop report). J Dent Res 83:744-750, 2004.

58. Barnett, M.L. Corporate support of advanced dental education: promise and pitfalls. J Dent Educ. Submitted for publication.

GUEST EDITORIALS:

1. Barnett, M.L.: The future isn't what it used to be - whither the new technologies? J. Dent. Res. 73:1234-1235, 1994.
2. Barnett, M.L.: The mouth that roared: Effective advocacy in the nineties and beyond. J. Dent. Res. 74:1148-1149, 1995.
3. Barnett, M.L.: Why is biomedical research like a washing machine? A question whose time has come. J. Dent. Res. 74:1340-1341, 1995.
4. Barnett, M.L.: The three rules of life: Some modest advice for those embarking on a career in dental research. J. Dent. Res. 74:1628-1629, 1995.
5. Barnett, M.L.: The assessment of new biotechnologies: Would the world be different if Napoleon had received recombinant growth hormone? J. Dent. Res. 74:1820-1821, 1995.
6. Barnett, M.L.: Responsible public communication: On how not to become a clown in the media circus. J. Dent. Res. 75:1528-1529, 1996.
7. Barnett, M.L.: The impact of language on our perceptions as dental researchers: Why do we remove "plaques" from teeth but add them to our walls? J. Dent. Res. 75:864-865, 1996.
8. Barnett, M.L.: Three new rules of life: Some additional modest advice for those embarking on a career in dental research. J. Dent. Res. 75:960-961, 1996.
9. Barnett, M.L.: Alternative medicine: More than chicken soup? J. Dent. Res. 75:1721-1722, 1996.
10. Barnett, M.L. and Mathisen, A.: Tyranny of the p-value: The conflict between statistical significance and common sense. J. Dent. Res. 76:534-536, 1997.
11. Barnett, M.L.: Molecular approaches to oral therapeutics: Dentistry in the next millenium? J. Dent. Res. 76:1236-1238, 1997.
12. Barnett, M.L.: Dental mythology and the Institute of Medicine Report. J. Dent. Res. 76:1524-1525, 1997.
13. Barnett, M.L.: From chromatograph to cuspid: Dental clinical research and the future of technology transfer. J. Dent. Res. 76:1812-1813, 1997.
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